

Adopt Ph 300, previously effective 10-23-14 (Doc. #10702, Interim), and expired 4-21-15, to read as follows:

## CHAPTER Ph 300 LICENSING OF PHARMACISTS AND PHARMACIES

### PART Ph 301 LICENSING OF PHARMACISTS BY EXAMINATION

#### Ph 301.01 Application.

(a) Application form Ph A-1 for licensure to practice the profession of pharmacy in New Hampshire may be obtained from the board or the board website;

(b) Applicants for licensure shall submit a completed form A-1 application for licensure and file it at the office of the board identified in Ph 103.03 along with:

- (1) A copy of the candidate's birth certificate;
- (2) A recent, full face photograph of the candidate;
- (3) An official final transcript sent directly from the college to the board office; and
- (4) The prescribed fee which shall be \$265.

(c) An official final transcript shall be mailed directly from the college to the board before either NAPLEX scores or New Hampshire licensure status is released, or, if a foreign graduate, the foreign graduate shall have completed a transcript verification program as provided by FPGEC certification.

(d) The photograph required by Ph 301.01 (b)(9) shall be attached to the application form in the presence of a notary public or justice of the peace.

Ph 301.02 Additional Requirements. In addition to any requirements imposed by statute, all candidates for a license to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character, and not have been convicted of any felony, or of a misdemeanor resulting from a violation of any drug and/or pharmacy-related law or rule;
- (c) The candidate shall have graduated with a professional pharmacy baccalaureate degree or a doctor of pharmacy degree granted by a school of pharmacy, or a college of pharmacy, or a department of a pharmacy of a university;
- (d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American or Canadian Council on Pharmaceutical Education.
- (e) If a foreign graduate, in lieu of (c) and (d) above, the candidate shall have graduated from a foreign college of pharmacy other than Canada and have obtained full certification from the FPGEC including:

- (1) Passing the FPGEE with a score of at least 75; and
- (2) Demonstrating proficiency in english by passing the Test Of English as a Foreign Language (TOEFL) with a score of at least 550.

(f) Prior to the examination date, the candidate shall have completed an internship in pharmacy and complete form A3 and submit to the board which shall:

(1) Consist of at least 1500 hours, starting no earlier than 4 months prior to the third year of study in a college of pharmacy; and

(2) Consist of work predominantly related to the practice of pharmacy including, but not limited to:

- a. The selling of drugs and medical supplies;
- b. Interpreting, compounding, preparing and dispensing prescription orders;
- c. Preparing pharmaceutical products; and
- d. Keeping records and preparing reports required by federal and state statutes.

(g) The candidate shall complete and pass the examination described in Ph 301.03.

Ph 301.03 Examination Contents. The examination required by Ph 301.02 shall be the National Association of Boards of Pharmacy Licensure Examination (NAPLEX) consisting of competency testing areas of:

- (a) Pharmacy theory;
- (b) Applied or practical pharmacy;
- (c) Pharmacology; and
- (d) Mathematics and chemistry.

Ph 301.04 Scheduling of Examinations.

(a) Except as provided in (b) below, the pharmacy examination shall be administered by the board. Upon request, the board shall notify the candidate of the date of the next scheduled examination. Failure of the candidate to sit for the examination at the required time shall result in denial of the application.

(b) Instead of requiring a candidate to take the complete pharmacy examination in the state of New Hampshire, the board shall accept, as equivalent to an examination administered by the board, the score attained by a candidate on a NAPLEX examination administered by the pharmacy licensing authority of some other state, but only if:

(1) The examination was administered in that other state in accordance with a degree of security which was equivalent to or greater than the security employed in the administration of examinations by this board;

(2) This board receives directly from the National Association of Boards of Pharmacy the score the candidate obtained on the NAPLEX examination;

(3) The candidate successfully completes the MPJE examination administered by the board and any other requirement for licensure, within 6 months from the date the New Hampshire application is mailed by the board office to the candidate; and

- (4) The candidate delivers to the board, with, or before, the transferred scores, the prescribed fee of \$265.

Ph 301.05 Required Examination Score. To successfully complete the examination required by Ph 301.02, the candidate shall, in the initial examination or any subsequent re-examination permitted by Ph 301.06, obtain a score of not less than 75. The passing score for the MPJE examination shall be 75 and shall not be reflected in the NAPLEX examination score.

Ph 301.06 Notice and Election of Re-examination.

(a) Any candidate who fails to obtain the minimum required score may elect to retake the examination.

(b) All candidates shall notify the board in writing whether he/she elects to be re-examined. The request for re-examination shall be accompanied by the prescribed fee as established by Ph 301.01 (b)(11).

(c) Any re-examination permitted by this section shall be administered by the board. Upon request by the candidate, the board shall notify the candidate of the next available dates of re-examination.

Ph 301.07 Issuance or Denial of Original License.

(a) If candidate timely files an application, complete in all respects, successfully completes all examinations required by Ph 301 and demonstrates the complete fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for an original license to practice pharmacy in New Hampshire fails to meet the requirements of these rules, or RSA 318, or both, the board shall deliver to the applicant a written denial of the application, specifying in detail the requirement which the candidate failed to meet, and how the candidate is deficient.

PART Ph 302 LICENSING OF PHARMACISTS BY RECIPROCITY

Ph 302.01 Reciprocity.

(a) Instead of sitting for the entire licensing examination required by Ph 301.02, a candidate may transfer the actual scores he or she attained on the NAPLEX administered by a state other than New Hampshire, providing that:

- (1) The candidate was issued a license to practice the profession of pharmacy in that state by reason of that examination;
- (2) The candidate is still duly licensed and is in good standing in that state; and
- (3) All other New Hampshire pharmacist licensing requirements have been met.

Ph 302.02 Application.

(a) The preliminary application for reciprocal licensure may be obtained from a link provided on the NH board of pharmacy website or from the National Association of Boards of Pharmacy, 1600

Feehanville Drive, Mount Prospect, Illinois, 60056, (847) 391-4406. This application shall be filed with the National Association of Boards of Pharmacy.

(b) Following verification of the applicant's credentials by NABP the applicant will receive an official NABP license transfer application in the mail.

(c) The candidate shall file a completed application NABP license transfer application provided by the National Association of Boards of Pharmacy along with NH form A-1, revised February 2015, and application for initial licensure as a pharmacist in NH; and attach the following:

- (1) A copy of the candidate's birth certificate;
- (2) A recent, full-face photograph of the candidate attached to the application;
- (3) An official copy of the candidate's pharmacy college transcript mailed directly from the college to the board; or if a foreign graduate, certification from the FPGEC; and
- (4) The application fee of \$265.

Ph 302.03 Requirements. In addition to any requirements imposed by statute, all candidates for licensure by reciprocity to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character as evidenced by the absence of conviction of any felony or of a misdemeanor resulting from a violation of any drug and/or pharmacy related law or rule;
- (c) The candidate shall possess a professional pharmacy baccalaureate degree or a doctor of pharmacy degree (Pharm.D.) granted by a school of pharmacy, or a college of pharmacy, or a department of pharmacy of a university; and
- (d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American or Canadian Council on Pharmaceutical Education;
- (e) A candidate who is a foreign pharmacy graduate, in lieu of (c) and (d) above, shall provide written documentation that such candidate has:
  - (1) Obtained full certification from the FPGEC; and
  - (2) Passed NAPLEX.
- (f) The candidate shall be licensed by examination and in good standing in the state from which he or she is seeking licensure transfer;
- (g) Candidates shall have obtained scores equivalent to the New Hampshire standards at the time the candidate was initially examined in the state in which he or she holds a current license; and
- (h) The candidate for a reciprocal license shall complete and pass the MPJE examination on the current federal and state laws and rules governing the practice of pharmacy in the state of New Hampshire.

Ph 302.04 Reciprocity Application Procedure. Once the application has been received in the board office the candidate shall be provided with copies of the "Pharmacy Law Handbook" and rules.

Ph 302.05 Reciprocity Application Time Limitation. Candidates who fail to complete the MPJE examination, as required by Ph 302.04(h), within 90 days after the candidate's application is received at the board office shall have their applications denied, but fees shall be retained by the board. If a candidate wishes to re-apply for New Hampshire licensure, a new application containing updated information shall be filed with the board.

Ph 302.06 MPJE Examination Required Scores and Fees.

(a) To successfully complete the examination required by Ph 302.04(h), the candidate shall, in the initial examination or any subsequent re-examination, obtain a score of not less than 75.

(b) The candidate shall pay the current examination fee to, and as assessed by, NABP.

Ph 302.07 MPJE Re-Examination Notice and Election.

(a) Any candidate who has failed to attain the minimum score in the MPJE examination as required by Ph 302.07, shall notify the board whether he or she elects to be re-examined.

(b) Any re-examination permitted by this section shall be administered on a date and at a time convenient to the candidate and the board, but no later than 60 days after the date of notification that the candidate failed to attain the minimum score as required by Ph 302.07.

(c) Any candidate for re-examination of the MPJE examination shall remit the current examination fee to NABP prior to being re-examined.

Ph 302.08 Reciprocity License Issuance or Denial.

(a) If a candidate timely files an application, complete in all respects and meeting the requirements of Ph 302, and demonstrate the fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for a reciprocity license to practice pharmacy in New Hampshire fails to meet the requirements of these rules or RSA 318, or both, the board shall deliver to the candidate a written denial of the application, specifying in detail each requirement which the candidate failed to meet, and how the candidate is deficient.

Ph 302.09 Certification of Scores/Licensure. Upon written request of the licensee, the board shall certify scores attained by the licensee in all pharmacy examinations administered by the board or that the licensee is duly licensed to practice the profession of pharmacy in New Hampshire. The written request shall contain the complete name and license number, if any, of the licensee.

PART Ph 303 PHARMACY PERMIT OPTIONS

Ph 303.01 Licensing the Entire Store Area.

(a) The pharmacy shall include the prescription department and all other retail sections of the store.

(b) The entire pharmacy shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public, according to Ph 702.04.

(c) The prescription department shall not be closed while the balance of the establishment remains open.

(d) A licensed pharmacist shall be on duty at all times when the pharmacy is open to the public.

Ph 303.02 Licensing Only the Prescription Department.

(a) The pharmacy shall include only the prescription department where drugs, chemicals, medicines, prescriptions are stored, compounded and dispensed. This area shall not include the other retail sections of the store the principle business of which is not the practice of pharmacy.

(b) The prescription department described in (a), above, shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public according to Ph 702.04.

(c) The prescription department may be closed while the remainder of the business establishment remains open to the public. During such periods, the pharmacy shall comply with Ph 702.04.

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public and during any absences by the pharmacist, the prescription department shall be secured except as is provided in Ph 704.01(b).

(e) Whenever the prescription department is closed, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in the pharmacy area. Such sign shall be composed of 3" lettering.

(f) Whenever the pharmacy is closed, prescriptions may be left via a mail slot which falls directly into the pharmacy area.

(g) The prescription mail slot:

(1) Shall be constructed so as to accept only a written or typed prescription or a notation of the prescription number for refills;

(2) Shall be no larger than 8" X 1" and designed so that prescriptions or notations, once deposited, cannot be retrieved by hand or by mechanical means; and

(3) Shall be constructed so as to deliver these prescriptions or notations directly into the prescription area for access by the pharmacist only so that they are not visible to the general public.

(h) No prescription, new or refill, shall be left with or accepted by clerks, pharmacy technicians as defined in RSA 318:1, XI-b or pharmacy interns as provided in RSA 318:42, IX when the prescription department is closed except as is provided in Ph 704.01(b).

(i) No finished prescriptions shall be left outside of the pharmacy area prescription department for pick-up when the prescription department is closed.

(j) No telephone prescriptions, new or refill, shall be accepted by clerks, pharmacy technicians or pharmacy interns when the prescription department is closed except as is provided in Ph 704.01(b).

(k) All drug order deliveries containing prescription drugs shall be delivered only when the prescription department is open and/or a licensed pharmacist is on the premises in order to secure such drug orders.

(l) A barrier preventing access to the prescription department by the public, shall be erected pursuant to the security requirements of Ph 702.04.

(m) Only New Hampshire licensed pharmacists employed by the pharmacy may be designated by the pharmacist-in-charge to have keys, and a list of these individuals shall be communicated to the board of pharmacy in writing whenever changes occur.

(n) All prescription departments licensed under this section shall be so equipped with a physical barrier from floor to ceiling capable of being locked and alarmed, separate from the rest of the store, to be utilized when the prescription department is not opened to the public.

Ph 303.03 Conversion of Pharmacy Permit. Conversion from licensure of the entire store to licensure of only the prescription department shall require:

(a) Plans be submitted for review by compliance assuring renovations meet the requirements of Ph 303.02(l) and Ph 303.02(n) before renovations begin; and

(b) Once completed, a new application form A-3, pursuant to Ph 306.05, together with the prescribed fee of \$250, shall be submitted to the board. This form shall be processed and a new pharmacy permit issued before the pharmacy department may open different hours from the remainder of the establishment.

#### PART Ph 304 ORIGINAL PHARMACY PERMIT APPLICATION

Ph 304.01 Obtaining and Filing a Permit Application. Application A-3 for a permit to operate a pharmacy in New Hampshire may be obtained from the board or board website, and shall be filed at, the board office, identified in Ph 103.03.

Ph 304.02 Application Contents.

(a) The applicant for a permit to operate a pharmacy in New Hampshire, shall supply a completed form A-3 revised February 2015.

(b) The applicant shall also submit scale drawings of the pharmacy, detailing usage of all space.

(c) The applicant shall supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements of Ph 304.

(d) The applicant shall submit a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) The application shall be filed with the prescribed fee of \$250.

#### PART Ph 305 ORIGINAL PERMIT PROCEDURE

Ph 305.01 Original Permit Conference.

(a) In addition to all requirements set forth in the statutes and elsewhere in this chapter, each applicant applying for a permit to operate a pharmacy in New Hampshire shall appear before the board for an informal conference to review the responsibilities of the pharmacist-in-charge and permit holder.

(b) If the owner is not the pharmacist-in-charge, then the owner or an officer of the corporation, or the district manager, as well as the anticipated pharmacist-in-charge shall appear before the board.

**Ph 305.02 Site Inspection for Original Permit.**

(a) Following the applicant's conference, the proposed site shall be inspected by one or more board members or compliance inspectors to determine if the premises are secure and suitable, as set forth in the NH pharmacy application information according to the provisions of Ph 702, for the operation of a pharmacy and that the required professional library material, according to Ph 702.07 (c) & (d), is available.

(b) Within the 60 day period after the issuance of the temporary permit as required by Ph 305.03, an inspector or a board member or both shall inspect the pharmacy. The full operation of the pharmacy shall be examined for compliance with federal and state statutes and rules governing the practice of pharmacy to ensure public protection.

**Ph 305.03 Issuance and Denial of Original Permit.**

(a) Applicants shall file a completed application at least 30 days before consideration will be given for a temporary permit.

(b) Providing that, the premises are suitable, according to Ph 305.02 (a), for the operation of a pharmacy and the applicant has met all other requirements of these rules and RSA 318, the applicant shall be granted a temporary permit which shall expire in 60 days. The temporary permit shall authorize the operation of a pharmacy only in the location and only under the name specified in the permit and shall authorize the pharmacist-in-charge to buy, possess and dispense prescription drugs, chemicals and pharmaceuticals.

(c) After consideration of the application and the report of the primary site inspection, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board documents evidencing the correction of those deficiencies. In the absence of a timely filing of documentation, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

**PART Ph 306 PERMITS - CHANGES IN SUPPORTING DATA**

**Ph 306.01 Pharmacy Ownership Transfer.** A transfer of ownership shall include any of the following:

- (a) The sale of the pharmacy;
- (b) The addition or deletion of one or more partners in a partnership;
- (c) The death of a singular owner; or



(d) In a publicly traded, multi-tiered corporation, a change in the corporate ownership of the majority or controlling interest of the lowest tier of the corporate structure doing business as a pharmacy in the State of New Hampshire.

Ph 306.02 Reporting Changes. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall, within 15 days of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing. An original new permit application, form A-3 shall be filed in addition to the written notice when the name, location, ownership, licensed area or pharmacist in charge of the pharmacy is changed.

Ph 306.03 Change in Pharmacy Name or Location - Prohibited. No person shall operate a pharmacy under a name, or at a location, different from the name and location contained in the permit issued pursuant to Ph 304, or an amendment of that permit issued pursuant to Ph 305.

Ph 306.04 Renovations. Plans for any renovation at any time after an original permit is issued shall be filed with the board for review and approval before proceeding with such changes.

Ph 306.05 Amending Permit Application Contents and Where Filed.

(a) Each applicant for amending a pharmacy permit for the purpose of a change of pharmacist-in-charge, a pharmacy name change or a licensed area change shall make and file a new permit application, form Ph A-3.

(b) Applicants filing a form Ph A-3 shall supply at least the following:

- (1) The type of change requested;
- (2) The names of the prior and current/new pharmacist-in-charge;
- (3) The names of pharmacist(s) on staff;
- (4) The date changes will be effective;
- (5) The pharmacy's hours;
- (6) A record of convictions or any findings of violations of pharmacy or drug related law against any individual or corporation named in this application; and
- (7) Signature of the pharmacist-in-charge and date signed.

(c) The application shall be filed at the board office identified in Ph 103.03 and submitted with the prescribed fee of \$250.

Ph 306.06 Issuance and Denial of Amended Permits.

(a) If a registrant shall file an application, complete in all respects, the board shall issue an amended permit. Upon receipt of this new permit, the licensee's existing permit shall be returned to the board office identified in Ph 103.03. Upon receipt of that amended permit the registrant shall operate the pharmacy under that amended permit.

(b) After consideration of the application, the board shall notify the licensee in writing of any deficiencies in the application. The licensee shall, within 20 days of the notice of deficiency, deliver to the board documentation evidencing the correction of those deficiencies. In the absence of a timely filing

of that documentation, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

#### PART Ph 307 RENEWAL AND REPLACEMENT PERMITS

Ph 307.01 Renewal Permits Required. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall renew that permit by December 31<sup>st</sup> of each year.

Ph 307.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at the board office.

Ph 307.03 Renewal Application Contents and When Filed.

(a) Applications for renewal of a permit to operate a pharmacy in New Hampshire shall consist of the prescribed form Ph A-3 as specified in Ph 304.02 and the prescribed fee of \$250.

(b) Renewal applications as required pursuant to Ph 307.01 shall be submitted to the board office identified in Ph 103.03 no later than the 15th day of December of each year.

Ph 307.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to how the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or the renewal shall be denied.

Ph 307.05 Issuance or Denial of Renewal Permit.

(a) If an applicant shall timely file an application, complete in all respects, and shall demonstrate the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application which continues to fail to meet the requirements of these rules and RSA 318 shall, after the notice and opportunity for hearing provided in Ph 307.04, be denied.

Ph 307.06 Replacement Permit Application and Contents.

(a) The holder of a current permit to operate a pharmacy in New Hampshire, whose permit has been lost or destroyed shall apply for a replacement permit within 15 days after the date the licensee discovers, or with reasonable diligence, should have discovered, the loss or destruction of the permit. There shall be no form prescribed for an application for a replacement permit.

(b) The request for a replacement permit shall:

- (1) Be in writing;
- (2) Contain the number of the current permit held by the applicant, if known;
- (3) Be accompanied by the remains, if any, of the permit for which a replacement is sought;
- (4) Be accompanied by the prescribed fee of \$25; and
- (5) Be filed at the board office.

#### PART Ph 308 REVOCATION AND SUSPENSION

Ph 308.01 Grounds for Revocation or Suspension. The board may revoke or suspend a permit to operate a pharmacy for grounds which include but are not limited to:

- (a) Misconduct as described in RSA 318:29, II (a thru g);
- (b) Violations of the provisions of RSA 318:29, V (a thru h).

Ph 308.02 Effect of Revocation.

(a) The revocation of a pharmacy permit shall permanently withdraw the authority to operate a pharmacy in New Hampshire.

(b) A subsequent permit may be obtained only by:

- (1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacies;
- (2) Paying all penalties assessed in connection with the cause for revocation; and
- (3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 308.03 Effect of Suspension.

(a) The suspension of a pharmacy permit shall temporarily withdraw the authority to operate a pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to operate a pharmacy in New Hampshire shall be recovered only by;

- (1) Complying with all of the requirements specified in the order of suspension;
- (2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a pharmacy permit; and
- (3) Paying all penalties assessed in connection with the cause for suspension.

Ph 308.04 Voluntary Surrender When Permitted.

(a) Any person holding a pharmacy permit may voluntarily return that permit to the board.

(b) The return of such permit shall be accompanied by the licensee's signed, written statement as to why the permit is being voluntarily returned to the board.

(c) The voluntary surrender of a permit to operate a pharmacy in New Hampshire shall serve to withdraw the authority for the licensee to operate that pharmacy in New Hampshire.

(d) Voluntary surrender of a permit to operate a pharmacy in New Hampshire shall not be permitted if there exists, at the time the permit is presented to the board, any cause for involuntary revocation or suspension of the licensee's permit to operate a pharmacy, unless the licensee presenting the permit shall state in writing that the voluntarily surrendered permit is in lieu of proceedings for the involuntary revocation or suspension of the permit to operate a pharmacy in New Hampshire.

Ph 308.05 Hearing. Except as authorized by statute or these rules, a permittee to operate a pharmacy in New Hampshire shall not be disciplined except after notice and opportunity for hearing provided by Ph 200.

Ph 308.06 Other Licensing Fees. The annual licensing fee for federally funded clinics under the direction of the department of health and human services shall be \$150 and for drug abuse treatment centers shall be \$150.

## PART Ph 309 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

### Ph 309.01 License Required.

(a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the board according to RSA 318:51-a. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if he is acting in the usual course of his business or employment.

(c) The board shall provide, on an annual basis, a license renewal form to all licensed manufacturers and wholesale distributors of prescription drugs and devices.

(d) The prescribed fee for original and annual renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be \$250.

Ph 309.02 Obtaining and Filing a License Application. Applications for licensure of manufacturers, wholesalers and distributors may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

Ph 309.03 Application Contents. The applicant for licensure shall supply, on form Ph A-5, at least the following information:

- (a) Name of the company;
- (b) The address of the actual location where manufacturing, wholesaling and distribution occurs;
- (c) Identification of ownership; and
- (d) Name and address of the person responsible for licensing.

Ph 309.04 Storage Conditions. All facilities at which prescription drugs are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions. All prescription drugs or chemicals shall be stored at appropriate temperatures per label requirements or in compliance with the latest edition of the official United States Pharmacopeia (USP)

compendium requirements to help ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, prescription drugs may be stored at room temperature in compliance with U.S.P. definition for room temperature. A separate storage section shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.

Ph 309.05 Facilities.

(a) All buildings in which prescription drugs are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning and maintenance.

(b) Buildings shall meet all applicable federal, state, and local standards. A facility shall not be located in a residence. All facilities shall be located in an area that is commercially zoned.

(c) A wholesale drug distribution facility shall notify the local police department or other appropriate law enforcement agency that it is a distributor of prescription drug products and controlled substances.

Ph 309.06 Security.

(a) Each wholesale drug distribution center shall be equipped with an internal alarm system to detect entry after hours. The alarm system shall be of the type that transmits a signal directly to a central station protection company, to a local or state police agency that has a legal duty to respond, a 24 hour control station operated by the wholesale drug distributor.

(b) Manufacturers and wholesale drug distributors shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide protection against theft by personnel.

Ph 309.07 Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of prescription drugs shall be maintained and made available for inspection by the board's inspectors for a period of 2 years.

(b) Records may be kept at a central location rather than at each distribution center, but records shall be made available for inspection within 72 hours of request by the board's inspectors.

Ph 309.08 Inspections.

(a) Inspections shall be performed by the board's inspectors and be conducted at the request of the board.

(b) Inspections shall be conducted during normal business hours, and notification of inspections shall be given no less than 48 hours in advance.

(c) Information that is considered to contain trade secrets or which might be proprietary in nature shall be protected from public disclosure.

Ph 309.09 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the manufacturer and wholesale drug distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state or national emergency.

(b) Written policies and procedures described in (a) above shall also provide for:

- (1) The management and correction of all errors or inaccuracies in inventories;
- (2) The assurance that any outdated stock, or any stock with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the manufacturer or otherwise destroyed; and
- (3) The control over the shipping and receiving of all stock within the operation.

(c) A copy of the policies and procedures, or sections thereof, shall be made available to the board upon request.

Ph 309.10 Returned Goods. A wholesale operation shall maintain a procedure for the proper handling and disposal of returned goods.

Ph 309.11 Handling Recalls.

(a) A wholesale operation shall maintain a written policy for handling recalls and withdrawals for products.

(b) Policies required by (a) above shall cover all recalls and withdrawals of prescription drug products due to:

- (1) Any voluntary action on the part of the manufacturer;
- (2) The direction of the Food and Drug Administration, or any other federal, state or local governmental agency; and
- (3) Replacement of existing merchandise with an improved product or new package design.

Ph 309.12 Responsibility for Operation. A wholesale drug distribution operation shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

Ph 309.13 Compliance with State and Federal Law.

(a) All manufacturers, wholesalers and distributors shall comply with all applicable state and federal laws and regulations.

(b) All manufacturers, wholesalers and distributors, doing business in New Hampshire, shall, before shipping or distributing any prescription drug, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All manufacturers, wholesalers and distributors, licensed and doing business in the state of New Hampshire, shall not provide unsolicited controlled drug samples to licensed practitioners.

(d) A manufacturer's license shall allow for the direct wholesaling or distribution of such drugs to other licensed or authorized recipients.

(e) A duly authorized agent of a manufacturer, wholesaler or distributor licensed in this state, may possess and distribute potent or prescription drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the manufacturer, wholesaler or distributor.

(f) Indirect sale or distribution shall include, but not be limited to:

(1) Solicitation, in this state, by manufacturers, wholesalers or distributors sales representatives;

(2) Telephone solicitations to customers located in this state by manufacturers, wholesalers or distributors sales representatives;

(3) Solicitation of customers located in this state by mail or by the use of media advertising which has a significant circulation in the state of New Hampshire.

Ph 309.14 Violations.

(a) No manufacturer or wholesaler shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(b) Any person who manufacturers, wholesales, or otherwise distributes prescription drugs, according to RSA 318:51-a and the provisions of Ph 309, shall be subject to disciplinary action as provided in RSA 318:29.

**APPENDIX**

Ph 301.01	RSA 318:5-a, I, III; RSA 318:18
Ph 301.02	RSA 318:5-a, II; RSA 318:18; RSA 318:19
Ph 301.03	RSA 318:5-a, I; RSA 318:10; RSA 318:18
Ph 301.04	RSA 318:5-a, IV; RSA 318:10
Ph 301.05	RSA 318:5-a, IV
Ph 301.06, Ph 301.07	RSA 318:10; RSA 318:18, II; RSA 318:29, I
Ph 302.01	RSA 318:21
Ph 302.02	RSA 318:21, RSA 318:5-a VII
Ph 302.03	RSA 318:21
Ph 302.04, Ph 302.05, Ph 302.06	RSA 318:21; RSA 318:5-a VII
Ph 302.07	RSA 318:5-a, VII
Ph 302.08, Ph 302.09	RSA 318:5-a, IV
Ph 303	RSA 318:5-a, I, II, IV-a, V, VII
Ph 303.02 (d), (h), and (j)	RSA 318:5-a, XIV
Ph 304.01	RSA 318:38, I, II, III
Ph 304.02	RSA 318:39
Ph 305 – 306	RSA 318-B:23
Ph 306.01 (d)	RSA 318:5-a, II and IV-a
Ph 307	RSA 318-B:25
Ph 308	RSA 318:5-a, VII
Ph 309	RSA 318:5-a, I, II, III, V, VII; RSA 318:42, III; RSA 318:51-a; RSA 318-B:3; RSA 318-B:5